DEC 17 2003

K033666

h. 510(k) Summary of Safety and Effectiveness

1. General Company Information

Name:	Medafor, Inc.
Address:	2700 Freeway Blvd Suite 800 Minneapolis, MN 55430
Telephone:	763/ 571-6300
FAX:	763/571-1035
Contact:	Jennifer May, Manager, Regulatory Affairs
Date Prepared:	December 12, 2003.

2. General Device Information

Product Name: Hemospheres™)	HemaDerm™ containing MPH (Microporous Polysaccharide
Classification:	Dressing, Unclassified, Product Code – FRO

3. Predicate Devices

Manufacturer / Product name
Medafor, Inc. / HemaDerm
Xomed, Inc. / MeroGel Control Gel ENT Surgical Dressing
Genzyme Corp. / SepraGel Sinus
ConvaTec / HA Absorbent Wound Dressing
T Scientific / T Pad
BioLife / Nosebleed QR powder
Marine Polymers / ProDien Patch
DeRoyal, Inc. / Single and Double Strung Tonsil Sponges and Double Strung Cylindrical Sponges
RITMED, Inc. / Floet Tonsil and Adenoid Sponges
Applied Therapeutics, Inc. / Rapid Rhino Nasal Pac with Gel Knit
Boston Medical Products / Rhinocell Nasal Packings
Les Laboratoires Brothier S.A. / ENTaxis Nasal Packing
BIOMATRIX,Inc. / Hylasine

See attached predicate matrix for details.

4. Description

Medafor, Inc.'s HemaDerm™ consists of dry, sterile, controlled porosity, spherical particles manufactured from purified plant based polysaccharide. The porosity is controlled such that the particles act as molecular sieves excluding large proteins and cells.

The bleeding cessation is accomplished by the rapid dehydration and subsequent hemoconcentration of blood in contact with the particles. The concentration of serum proteins and cells produces a viscous gel. Normal platelet activation and fibrin deposition within the congealed blood produces a clot that limits further bleeding.

5. Indications

HemaDerm™ is intended for use under the care of a health care professional as a topical dressing for the temporary treatment of severely bleeding wounds such as surgical wounds (post-operative, donor sites, dermatological,) minor cuts, and lacerations and for the temporary treatment of mild bleeding from topical ENT surgical wounds and nosebleeds.

HemaDerm™ is intended for use under the care of a health care professional for the local management and control of bleeding from percutaneous needle access, vascular access sites and percutaneous catheters.

6. Substantial Equivalence

The primary predicate for this submission is the original 510(k) notification for HemaDerm (K021678, cleared July 12, 2002). The product which is the subject of this notification is **identical** to that product in the following respect:

- Warnings/Precautions/Contraindications
- Operating Principles
- Performance Specifications
- Materials
- Manufacturing
- Packaging Materials and Operations
- Sterilization Processing

Other predicates listed in this submission are for the areas of indications and intended use; all but one listed predicate is a prescription devices. Additional predicates for this notification include devices that are used to dress bleeding wounds for the areas addressed by the revised indications, i.e.: topical ear, nose, and throat locations including nosebleeds.

These predicate devices are indicated for use in ear, nose, and throat surgeries and/or for nosebleeds. HemaDerm is substantially equivalent to these predicate products in that it has a similar intended use and indications. The subject predicate devices are made from materials which have demonstrated satisfactory biocompatibility, are highly absorbent, and are sterile single use devices. HemaDerm has also been shown to be biocompatible, absorbent, sterile, and is packaged as a single use device. HemaDerm is different from these predicate devices in that it consists of Medafor's proprietary MPH beads, which have been shown to be safe and effective in earlier testing submitted in previous 510(k) notifications. Because of the similarities in intended uses to these products, Medafor believes that it is substantially equivalent to the predicate devices that have been reviewed, classified and approved or that are exempt from 510(k) submission.

Matrix of Predicate Devices

Manufacturer Product name	510(k)	Material	Indications /Description
Medafor, Inc. HemaDerm	K021678	Polysaccharide	HemaDerm™ is intended for use under the care of a health care professional as a topical dressing for the temporary treatment of severely bleeding wounds such as surgical wounds (post-operative, donor sites, dermatological), minor cuts and lacerations. HemaDerm™ is intended for use under the care of a health care professional for the local management and control of bleeding from percutaneous needle access, vascular access sites and percutaneous catheters.
Xomed MeroGel ENT Surgical Dressing	K002972	HYAFF, an ester of hyaluronic acid	MeroGel Control Gel ENT Surgical Dressing is a dressing and/or stent intended to separate tissues of structures compromised by surgical trauma, help control minimal bleeding, and act as an adjunct to aid in the natural healing process. The device is indicated for use in the ear, nose, and throat, head and neck surgical procedures where an open wound dressing and/or stenting material is required including the middle ear and external ear canal following myringoplasty, tympanoplasty, canalplasty, stapes and mastoid surgery, also for use in the nasal and/or sinus cavities following nasal, sinus, and/or throat surgery where separation of tissues or structures is desired.
Genzyme Hylasine (Sepragel Sinus)	K012532	Derivative hyaluronic acid	HylaSine is indicated for use in patients undergoing nasal/sinus surgery as a space-occupying gel stent to separate and prevent adhesions between mucosal surfaces in the nasal cavity, to help control minimal bleeding following surgery or nasal trauma, and to prevent lateralization of the middle turbinate during the postoperative period. HylaSine, hylan B is a sterile, transparent, viscoelastic gel composed of cross-linked polymers of hyaluranon. This hyaluranon is a bioresorbable material that functions to fill nasal/sinus cavities following surgery or trauma and to keep mucosal surfaces separate during the healing process. During this time, the tamponade effect helps control minimal bleeding normally associated with routine sinus surgery. HylaSIne leaves the sire of placement by natural elimination, or it may aspirated form the cavity earlier at the discretion of the physician.
Convatec HA Absorbent Wound Dressing-R	K984388	HYAFF 11p75, a benzyl ester of hyaluronic acid	HA Absorbent Wound Dressing-R is indicated for use in the management of deep exuding wounds, sinuses, and fistulae
T Scientific T-Pad	K030334	poly-N-acetyl glucosamine.	The T-Scientific T-Pad is intended for use in the local management of bleeding wounds such as lacerations, abrasions, nose bleeds, vascular access sites, percutaneous catheters or tubes and surgical debridement, and the promotion of rapid control of bleeding in patients following hemodialysis and in patients on anticoagulation therapy.
BioLife NoseBleed QR Powder	Class I exempt	potassium salt and hydrophilic polymers	For nosebleeds (only in the anterior nasal cavity) and hard to treat areas
Marine Polymers ProDein Patch	K984177	Polysaccharide/ poly-n-acetyl glucosamine	ProDein Patch is indicted for use in the local management of bleeding wounds such as lacerations, abrasions, and nosebleeds.
Les Laboratoires Brothier S.A ENTAxis Nasal Packing	K984069	calcium alginate	ENTaxis Nasal Packings are intended for nasal epistaxis and as post operative nasal packings.
DeRoyal, Inc. Single and Double Strung Tonsil Sponges and Double Strung Cylindrical Sponges	510(k) exempt; unknown,	Gauze covered cotton sponge plus Raypaque (x-ray detectable element)	Tonsil Sponges: The single/double strung tonsil sponge has 15" white memory free cotton string. Covered with gauze, the sponge is cotton filled for maximum absorbency and an Raypaque element within ensures x-ray detectability. Sterile. Double Strung Cylindrical Sponge: Highly absorbent, this cotton sponge is designed for tonsil, adenoid and nasal surgery. Designed with an Raypaque element inside, this sponge is x-ray detectable. Sterile.
RITMED, Inc. Floet Tonsil and Adenoid Sponges	K830264	Gauze covered super-absorbent non-woven cotton	Gauze covered super-absorbent non-woven cotton. Available sterile. Available double strung and stung on count card. All have x-ray element. Sizes include: ½", 7/8", 1", 1 ¼ " double strung and ½" x 1", ½ "x 1 ½", ¾" x 1 ½" stung on count card
Applied Therapeutics, Inc. Rapid Rhino Nasal Pac with Gel Knit	K000108	PVC catheter with carboxy-methylcellulose as the hemostatic material	Rapid Rhino is designed to control epistaxis due to: a) Trauma b) Post-operative bleeding c) Spontaneous epistaxis. It is intended to treat minor nasal bleeding. Controls minor bleeding via active platelet aggregation, when exposed to blood or fluids.
Boston Medical Products Rhinocell Nasal Packings	K972459	Lint and fiber free polyvinyl alcohol sponge material	For use as a nasal packing to treat epistaxis. Superior liquid absorption and wicking characteristics
BIOMATRIX,Inc. Hylasine	K993362	Sterile, transparent, viscoelastic gel composed f cross-linked polymers of hyaluron	The intended use of Hylasone is for use in nasal/sinus cavity as a space-occupying gel stent, to separate mucosal surface and to help control minimal bleeding following surgery or nasal trauma. Hylasinc leaves the site of placement by natural elimination, or it may be aspirated from the cavity earlier at the discretion of the physician.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2003

Medafor, Inc.
c/o Jennifer May
Regulatory Affairs
2700 Freeway Blvd.
Suite 800
Minneapolis, MN 55430

Re: K033666
Trade/Device Name: HemaDerm™
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 19, 2003
Received: November 21, 2003

Dear Ms. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Applicant: Medafor, Inc.

510(k) Number (if known):

Device name: HemaDerm™

Intended Use/Indications for Use:

HemaDerm™ is intended for use under the care of a health care professional as a topical dressing for the temporary treatment of severely bleeding wounds such as surgical wounds (post-operative, donor sites, dermatological,) minor cuts, and lacerations and for the temporary treatment of mild bleeding from topical ENT surgical wounds and nosebleeds.

HemaDerm™ is intended for use under the care of a health care professional for the local management and control of bleeding from percutaneous needle access, vascular access sites and percutaneous catheters.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____

(Per 21 CFR 801.109) (Optional Format 1-1-96)

(Division Sign-Off)
Division of Ophthalmic, Ear, Nose and Throat Devices

510(k) Number K033666